



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,138	11/19/2003	Kevin Delos Parris	2368/91	9179

26169 7590 01/09/2006
FISH & RICHARDSON P.C.
P.O BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

NASHED, NASHAAT T

ART UNIT PAPER NUMBER

1656

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/717,138	Applicant(s) PARRIS ET AL.	
	Examiner Nashaat T. Nashed, Ph. D.	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 34-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 34-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1656

The application has been amended as requested in the communication filed November 4, 2005. Accordingly, claims 1-7 and 34-48 have been amended, and claims 8-33 have been canceled.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s). In particular, 37 CFR 1.821, which states:

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

In response to similar objection in the previous Office action, mailed July 13, 2005, applicant attempted to comply with the sequence rule, but their efforts fail short with regard to Rule 37 CFR 1.821 (d). Applicants have the burden of identifying all the deficiencies in their application as they relate to the sequence rule and perfect their compliance with said rules. Thus, each time specific reference to a disclosed sequence in the sequence listing is cited in the specification such as ACP, ACPs or similar ones from other organisms a sequence identification number must be inserted next to the reference through out the specification, see for examples the paragraph bridging pages 4 and 5, page 5 paragraph 2, page 20, last line, Table 1, Table 2 at page 23, see page 25, page 26, line 5, and page 33.

The disclosure is objected to because of the following informalities: The specification at page 19 states: Optimization of a crystalline hit (2M potassium formate, 20% PEG 3350) gave diffraction quality rod shaped crystals. Crystals could be obtained between 0.15M and 0.3M potassium formate and between 15 and 23% PEG 3350. Those two sentences are confusing because the concentration of 2 M potassium formate in the optimized condition is not encompassed by the range in which crystals grow, i. e., 0.15-0.3 M.

Appropriate correction is required.

Claims 2-5 and 35-38 are objected to because of the following informalities: The claims refer to amino acid residues using capitalized three letter codes. This is not the conventional reference to amino acid residues using the three letter codes. The first letter of the three letter code is capitalized followed by the other two letter in small key, for example, Gly, His, Pheetc. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which

Art Unit: 1656

it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 34-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the prior Office action mailed, 7/14/05.

In response to the above rejection, applicant inserted the space group of the crystal and thought that would be sufficient to overcome the lack of written description.

Applicants' arguments filed November 4, 2005 have fully considered, but they are found unpersuasive. Regarding example 4 of the trilateral report cited by the applicant, the example does not provide any instruction regarding the written description requirement. Obviously, applicants recognized that the claim needed a structure element and amended the claim to define the crystal by the space group C222₁. The claims, however, contain two other structure elements that are not defined. They are the amino acid sequences of ACP and ACPS. The specification does not provide any teaching on how to change the crystallization conditions with changing the amino acid sequences, and hence, with their precipitation properties. The specification failed to provide any additional examples of any other crystals other than the crystal consisting of the complex of SEQ ID NO's: 1 and 2. The insertion of the amino acid sequences of SEQ ID NO's: 1 and 2 in claim 1 would obviate this rejection.

Claims 1-7 and 34-48 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for the reasons set forth in the prior Office action mailed, 7/14/05.

In response to the previous Office action, applicants have limited the claims to encompass only a crystal in space group C222₁, and listed their interpretation of the Wands factor.

Applicants' arguments filed November 4, 2005 have fully considered, but they are found unpersuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. The previous Office action sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning why a person of ordinary skill in the art would doubt that the guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants assert that the subject matter covered by the claims is no broader than applicants' contribution. Applicants

Art Unit: 1656

make no effort to explain why they consider the disclosure of a crystal consisting of a complex of SEQ ID NO: 1 and 2 in space group C222₁ is sufficient enablement for any crystal of a complex containing any ACP or ACPS including their mutants. Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1656